



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO | . 1 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------|-----------------------|-----------------------|----------------------|-------------------------|------------------|
| 09/723,000 | 09/723,000 11/27/2000 | | Jorg J. Goronzy | 07039-170002 | 4888 |
| 26191 | 7590 | 04/20/2004 | | EXAMINER | |
| FISH & R | | SON P.C. IER PLAZA | CHEN, STACY BROWN | | |
| | 60 SOUTH SIXTH STREET | | | | PAPER NUMBER |
| MINNEAP | OLIS, M | N 55402 | 1648 | | |
| | | | | DATE MAILED: 04/20/2004 | 4 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------|--|--|--|--|
| | | GORONZY ET AL. | | | | |
| Advisory Action | 09/723,000 | Art Unit | | | | |
| | Examiner Stacy B Chen | 1648 | | | | |
| The MAN INC DATE of this communication appe | _ | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address THE REPLY FILED 08 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. | | | | | | |
| Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. | | | | | | |
| PERIOD FOR REPLY [check either a) or b)] | | | | | | |
| a) The period for reply expires 3 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| 1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal. | | | | | | |
| 2. The proposed amendment(s) will not be entered because: | | | | | | |
| (a) they raise new issues that would require further consideration and/or search (see NOTE below); | | | | | | |
| (b) ☐ they raise the issue of new matter (see Note below); | | | | | | |
| (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or | | | | | | |
| (d) they present additional claims without canceling a corresponding number of finally rejected claims. | | | | | | |
| NOTE: | | | | | | |
| 3.⊠ Applicant's reply has overcome the following rejection(s): See Continuation Sheet. | | | | | | |
| 4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). | | | | | | |
| 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See Continuation Sheet</u> . | | | | | | |
| 6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection. | | | | | | |
| 7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. | | | | | | |
| The status of the claim(s) is (or will be) as follows: | | | | | | |
| Claim(s) allowed: | | | | | | |
| Claim(s) objected to: | | | | | | |
| Claim(s) rejected: <u>48-57 and 60-62</u> . | | | | | | |
| Claim(s) withdrawn from consideration: | | | | | | |
| 8. The drawing correction filed on is a) approved or b) disapproved by the Examiner. | | | | | | |
| 9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s) | | | | | | |
| 10. Other: | | | | | | |
| | | | | | | |
| | | | | | | |

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicant's amendment to the specification is acknowledged and the sequence information has been entered. The rejection of claims 48-57 and 60-62 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's response. The rejection of claims 48-57 and 60-62 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's repsonse. In a telephonic interview with Patrick Finn on March 3, 2004, the rejections of record were discussed. Applicant's representative explained that the nomenclature of the alleles (*0401, for example) in the claims is standard in the art. Also discussed was asserted novelty of the invention, which is that the measurement of CD4+/CD28null cell frequences and the measurement of HLA-DRB1 alleles are independent indicators of a disease state (arthritis).

Continuation of 5. does NOT place the application in condition for allowance because: Claims 48-57 and 60-62 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Goronzy et al. in view of Abril et al., for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that the claimed method requires two measurements: CD4+/CD28null cell frequencies and the presence/absence of particular HLA-DRB1 alleles. Applicant argues that the prior art fails to suggest a method combining both measurements to determine a disease state. Applicant cites Chapman et al., which teaches that CD4+/CD28null cell frequences are associated with the presence of HLA-DRB1 alleles. Applicant asserts that this teaching would lead one of ordinary skill to measure only CD4+/CD28null cell frequences, or the presence/absence of HLA-DRB1 allele, since one measurement would supposedly be sufficient to determine a disease state. In response, Abril teaches that CD28null cells suggest that genes controlling their expression represent disease risk genes. This teaching would have motivated one of ordinary skill to test for the presence/absence of Goronzy's alleles. Applicant argues that neither Goronzy nor Abril recognize that the measurements are independent of each other. However, such recognition is not required, since one would have been motivated to use both measurements, as is instantly claimed. With regard to Chapman, the Office notes that Chapman's method teaches measuring both cell frequencies and the presence/absence of HLA-DRB1 alleles. Although Chapman does not recognize that the measurements are independent of each other, Chapman performs both measurements, as is instantly claimed. Therefore, while the prior art is silent on the reasoning behind the claimed method, the prior art teaches the claimed method.

8PC 4/7/2004

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600